Congress of the United States
Washington, DC 20515

March 12, 2020

Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Stephen Hahn
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Secretary Azar,

As concerns regarding our capacity to test patients with the 2019 Novel Coronavirus (COVID-19) continue to rise, the agency must take all steps necessary to ensure that all collected samples of the disease are able to be tested. We have heard from our research labs run by the University of California that they are capable of supporting the medical community but need further guidance about the steps that these labs—and labs across the country—could take to be in compliance with requirements in place under the current public health emergency declaration. Considering the urgency of mitigating the rising spread of COVID-19, we ask that you expedite assistance and regulatory guidance for new, simple tests that can be easily performed in the medical setting.

In Washington state, where community spread is rampant, researchers who had the capacity to support clinical lab work were prevented from doing so. Dr. Helen Y. Chu, as part of an infectious disease research project into the flu, had been collecting nasal swabs from Washington residents displaying flu-like symptoms throughout the Puget Sound region.[1] Dr. Chu offered her team's services to federal and state officials to help increase the state's ability to test patients who may have been exposed to COVID-19; however, her team was unable to do so. Reports explained that, "federal and state officials said the flu study could not be repurposed because **it did not have explicit permission from research subjects; the labs were also not certified for clinical work**."[2] While patient privacy and clinical accuracy are of the utmost importance, it is time for the federal government to support research labs by providing the necessary waivers and expediting processes to remove restrictions that prevent labs and providers from testing samples collected from those displaying symptoms.

As another example, which is representative of many labs across America: the University of California Los Angeles's (UCLA) clinical lab is certified under the Clinical Laboratories Improvement Act and subsequent Amendments (CLIA) and is currently performing in-house testing following the Food and Drug Administration's (FDA) February guidance to help expedite testing.[3] The FDA can issue an Emergency Use Authorization (EUA) to allow the use of medical products that are effective in "diagnosing, treating or preventing a disease or condition" when the Secretary of Health and Human Services (HHS) determines that there is a public health emergency.[4] The policy issued in February specifically targets labs that develop and begin to use "validated" COVID-19 diagnostics before the FDA

[1] https://www.nytimes.com/2020/03/10/us/coronavirus-testing-delays.html?searchResultPosition=1
[2] https://www.nytimes.com/2020/03/10/us/coronavirus-testing-delays.html?searchResultPosition=1
[3] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics
[4] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics

has fully reviewed their EUA requests.[5] The guidance focuses on those labs pursuing an EUA with the FDA that were already CLIA-certified. While we do not support loosening the restrictions around CLIA, which are essential to patient safety, many academic medical centers have research labs that use the same testing equipment and have more capacity but are not CLIA-certified. We would like to request that the Administration, acting through CMS, work with these labs, and all of those nationally that are similarly situated, to help them become certified so that they can help expand our testing capabilities.

In order to further expand testing capacity and spread, we must develop the same sort of simple, rapid tests being used in South Korea and other countries. Current domestic testing is very complex, done in certified labs with specialized equipment by highly trained individuals. Other countries have simpler tests, akin to a flu test that can easily be run by a primary care provider's office. We would urge you to work with the companies and the labs that are in the process of developing a simpler test,[6] to help expedite an accurate, reliable, and valid test to the market as soon as possible.

Clinical accuracy is of the utmost importance, and we must do more to help ensure our communities are equipped and prepared to protect the health and safety of our communities. Continued delays in testing have made it virtually impossible for us to create a clear and precise picture of the scope of COVID-19's spread. As the number of cases continues to rise in California and across the country, we have a responsibility to ensure that we can test as many cases as possible – and this means assisting labs that stand ready to help.

Thank you for your attention to this critically important issue. Understanding the urgency of this request, we ask that you respond to this letter prior to March 18, 2020 with a clear and detailed report of your plan to expedite diagnostic testing.

Best,

KATIE PORTER
Member of Congress

JOHN GARAMENDI
Member of Congress

JERROLD NADLER
Member of Congress

MIKE THOMPSON
Member of Congress

***Please note that, out of an abundance of caution, only e-signatures were collected, so some signatures are not included.**

[5] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics

[6] https://www.evaluate.com/vantage/articles/news/policy-and-regulation/few-groups-have-developed-covid-19-diagnostics-will

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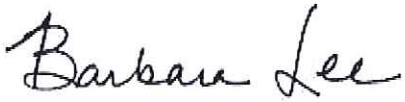

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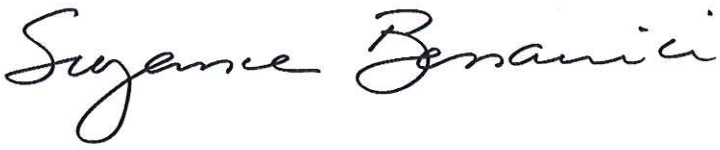

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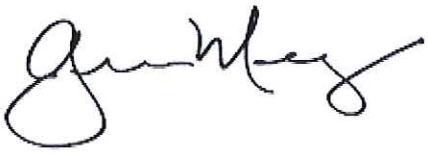

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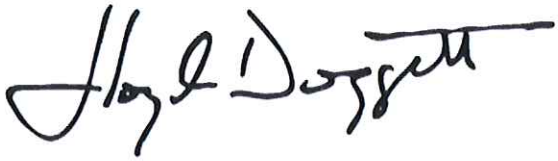

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